| 1 2 | Dena C. Sharp (State Bar No. 245869) Jordan Elias (State Bar No. 228731) Adam E. Polk (State Bar No. 273000) | Elizabeth J. Cabraser (State Bar No. 083151) Lexi J. Hazam (State Bar No. 224457) Sarah R. London (State Bar No. 267083) | | | | |
|-----|--|--|--|--|--|--|
| 3 | GIRARD SHARP LLP | Tiseme G. Zegeye (State Bar No. 319927) | | | | |
| 4 | 601 California Street, 14th Floor San Francisco, CA 94108 | LIEFF CABRASER HEIMANN & BERNSTEIN, LLP | | | | |
| 5 | Tel: (415) 981-4800 Fax: (415) 981-4846 | 275 Battery Street, 29th Floor San Francisco, CA 94111 | | | | |
| 6 | dsharp@girardsharp.com jelias@girardsharp.com | Tel: (415) 956-1000 Fax: (415) 956-1008 | | | | |
| 7 | apolk@girardsharp.com | ecabraser@lchb.com | | | | |
| 8 | Amy M. Zeman (State Bar No. 273100) | lhazam@lchb.com slondon@lchb.com | | | | |
| 9 | GIBBS LAW GROUP LLP 505 14th Street, Suite 1110 | tzegeye@lchb.com | | | | |
| 10 | Oakland, CA 94162 | | | | | |
| 11 | Tel: (510) 350-9700 amz@classlawgroup.com | | | | | |
| 12 | Adam B. Wolf (State Bar No. 215914) | | | | | |
| 13 | Tracey B. Cowan (State Bar No. 250053) | | | | | |
| 14 | PEIFFER WOLF CARR & KANE, A PROFESSIONAL LAW CORPORATION | | | | | |
| 15 | 4 Embarcadero Center, Suite 1400 San Francisco, CA 94111 | | | | | |
| 16 | Tel: (415) 766-3545 | | | | | |
| 17 | Fax: (415) 402-0058 awolf@pwcklegal.com | | | | | |
| 18 | | | | | | |
| 19 | Counsel for Plaintiffs and Interim Class Counsel | | | | | |
| 20 | [Additional Counsel on Signature Page] | | | | | |
| 21 | IINITED STATES | S DISTRICT COURT | | | | |
| 22 | UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA | | | | | |
| 23 | SAN FRANCISCO DIVISION | | | | | |
| 24 | IN RE PACIFIC FERTILITY CENTER) | Case No. 3:18-cv-01586-JSC | | | | |
| 25 | LITIGATION | | | | | |
| 26 | | FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT | | | | |
| 27 | | DEMAND FOR JURY TRIAL | | | | |
| 28 | <u> </u> | FILED UNDER SEAL | | | | |
| | | | | | | |

NATURE OF THE ACTION

| TA | RI | \mathbf{F} | \mathbf{OF} | CON | T | TIN | JTC |
|--------------|----|--------------|---------------|-----|-----|-----|-----|
| \mathbf{H} | DI | ır. | V)F | w | 7 I | | |

| | | ND VENUE | | |
|---|--|---|----|--|
| | | ASSIGNMENT | | |
| | | ASSIGNMENT | | |
| TAKTILS | A. | Plaintiffs | | |
| | В. | Defendants | | |
| | ٥. | 1. Prelude and Pacific MSO | | |
| | | 2. PFC | | |
| | | 3. Chart | | |
| FACTUAL A | ALLEG | ATIONS | | |
| I. Prelude Was Responsible for the Safe Storage of Plaintiffs' Eggs and Embryos Time of the Incident. | | | | |
| | A. | Background on Cryopreservation and Freezer Storage. | 7 | |
| | PFC markets cryopreservation and freezer storage services as an insurance policy | 8 | | |
| | C. | PFC represented on its website, and in sales and marketing materials, that it would keep Plaintiffs' eggs and embryos safe in a state-of-the-art facility | 9 | |
| | D. | PFC Relinquished its Storage Operation to Prelude in September 2017 Without Advising Plaintiffs. | 11 | |
| II. | | sion and Care Are Required in the Retrieval, Cryopreservation and Storage of and Embryos. | 12 | |
| | A. | The process of retrieving and storing eggs and embryos is demanding, time consuming, and expensive. | 12 | |
| | B. | The loss of eggs and embryos results in emotional distress, pain, and suffering. | 14 | |
| | C. | Successful cryopreservation and storage depend on strict adherence to protocols | 14 | |
| III. | | de Caused Irreparable Harm to Plaintiffs by Failing to Protect Their Eggs and ryos. | 16 | |
| | | i | | |

Case 3:18-cv-01586-JSC Document 196 Filed 04/03/19 Page 3 of 51

| A. | Prelude should have had systems and processes in place to ensure that Plaintiffs' eggs and embryos were not damaged. | 16 |
|------------------|--|------|
| В. | Chart recalled cryostorage tanks for vacuum seal defects after the Tank 4 incident | 17 |
| C. | Multiple investigations were opened after the Tank 4 incident | 18 |
| D. | Prelude's failure to keep Plaintiffs' eggs and embryos safe and secure has resulted in harm. | 18 |
| E. | PFC's communications regarding the incident have compounded the harm | 20 |
| PLAINTIFF-SPECII | FIC ALLEGATIONS | 22 |
| CLASS ACTION A | LLEGATIONS | 28 |
| CLAIMS FOR RELI | EF | 30 |
| | SE OF ACTION Negligence and/or Gross Negligence ude and Pacific MSO) | 30 |
| SECOND CA | AUSE OF ACTION Negligent Failure to Recall (Against Chart) | 33 |
| THIRD CAU | SE OF ACTION Bailment (Against Prelude and Pacific MSO) | 33 |
| FOURTH CA | AUSE OF ACTION Premises Liability (Against Prelude and Pacific MSO) | 34 |
| | SE OF ACTION Violations of the Unfair Competition Law ("UCL"), Prof. Code § 17200 et seq. (Against Prelude, Pacific MSO, Chart, and PFC) | 35 |
| | SE OF ACTION Violations of the Consumers Legal Remedies Act, Cal. Civ. et seq. (Against PFC, Prelude, and Pacific MSO) | 39 |
| | AUSE OF ACTION Fraudulent Concealment (Against PFC, Prelude, and | 42 |
| EIGHTH CA | USE OF ACTION Strict Products Liability – Failure to Warn (Against Chart). | 44 |
| | SE OF ACTION Strict Products Liability – Manufacturing Defect rt) | . 45 |
| | USE OF ACTION Strict Products Liability – Design Defect – Consumer Test (Against Chart) | 45 |
| | CAUSE OF ACTION Strict Products Liability – Design Defect – Risk-Utility Chart) | |
| PRAYER FOR REL | IEF | 46 |
| DEMAND FOR JUI | RY TRIAL | 47 |
| | ii | |

21

22

23

24

25

26

27

28

1

2

3

Plaintiffs A.B., C.D., E.F., G.H., I.J., K.L., M.N., and O.P. ("Plaintiffs"), individually and on behalf of all others similarly situated, file this First Amended Consolidated Class Action Complaint against Defendants Prelude Fertility, Inc. ("Prelude"), Pacific MSO, LLC ("Pacific MSO"), Chart, Inc. ("Chart"), and San Francisco Fertility Centers, d/b/a Pacific Fertility Center ("PFC"), and allege as follows:

NATURE OF THE ACTION

- 1. PFC markets and sells fertility services, including fertility treatment, egg and embryo cryopreservation, and long-term freezer storage services. On its website and in sales and marketing materials, PFC likens cryopreservation to an insurance policy for women and families, claiming the services provide peace of mind to those who wish to defer having children and relief to those seeking to overcome a diagnosis of infertility.
- 2. Cryopreservation involves preservation of tissue—here, human eggs and embryos using cooling techniques. In the 1980s, facilities began using a cryopreservation technique known as "slow freezing" to preserve human reproductive tissue. Cryopreservation became more prevalent after the advent in the early 2000s of vitrification, a process by which tissue is cooled more quickly, leading to higher egg and embryo survival rates. Eggs and embryos frozen through cryopreservation are stored in specially designed metal tanks.
- 3. The use of appropriate technologies and maintenance protocols is necessary to ensure the safekeeping of cryopreserved eggs and embryos. Safe long-term storage requires backup redundancies to guard against catastrophic failure, regular inspections of the tanks, and automated temperature and fill-level gauges linked to alarm systems to notify staff immediately of a potential failure.
- 4. Between 2010 and 2016 Plaintiffs decided to undergo fertility treatment at PFC and to procure long-term freezer storage services for their eggs and embryos at its San Francisco facility.
- 5. Unbeknownst to Plaintiffs, PFC entered into an agreement with Prelude, which operates a national network of egg and embryo long-term freezer storage facilities, in September 2017. Under that agreement, Prelude, an unlicensed, non-medical corporation, took over PFC's egg and embryo storage operation, agreeing as part of the transaction that Prelude and its operating subsidiary, Pacific

MSO (together, "Prelude"), would bear responsibility for determining how the storage services were performed. Prelude has no doctors on staff and provides only non-clinical services. Despite multiple opportunities to do so, neither PFC nor Prelude notified Plaintiffs of the Prelude-PFC transaction or that because of it, PFC (and the doctors it employs) were no longer responsible for the storage of Plaintiffs' eggs and embryos at its facility. Instead, on its website and in other sales and marketing materials, PFC continues to hold out Prelude's egg and embryo storage services as its own.

- 6. On March 4, 2018, Prelude discovered that the liquid nitrogen levels in a tank known as "Tank 4" had dropped to an unsafe level for an undetermined period of time, destroying or jeopardizing the eggs and embryos stored in the tank, including Plaintiffs' stored tissue. Chart manufactured Tank 4.
- 7. Plaintiffs were first notified of the Tank 4 failure via an email sent at approximately 4:00 a.m. Pacific time on Sunday, March 11, 2018. The email described the failure as "a very unfortunate incident" in which the storage tank containing Plaintiffs' cryopreserved eggs and embryos "lost liquid nitrogen for a brief period of time," and stated that a "preliminary analysis" suggested some of the eggs and embryos in the tank may have been destroyed. It has now been confirmed that a substantial portion of the eggs and embryos contained in Tank 4 were destroyed in the incident.
- 8. Over a month later, on April 19, 2018, Plaintiffs and others whose eggs and embryos had been stored in Tank 4 received another email—this time notifying them that an investigation had revealed that the incident "likely involved a failure of the tank's vacuum seal." Four days later, on April 23, 2018, Chart recalled several of its cryopreservation tanks, citing "reports of a vacuum leak or failure that could compromise the product."
- 9. As of March 4, 2018, Prelude bore responsibility for operating Tank 4, monitoring Tank 4's performance for fluctuations in temperature or liquid nitrogen levels, and maintaining safety and backup systems to mitigate any harm that a tank failure might cause. But Prelude failed to safely preserve the eggs and embryos under its care, including the eggs and embryos belonging to Plaintiffs.
- 10. As a result of the incident, Plaintiffs have suffered harm. For many, the tissue in Tank 4 represented their last and only chance for a biological child. PFC and Prelude have informed Plaintiffs that it is not possible to know whether their eggs or embryos are viable until they are thawed and (for eggs) fertilized and that, even then, the survival cannot be determined without attempting a pregnancy.

PFC has also warned the proposed class that attempted pregnancies with Tank 4 embryos may involve "additional risks [that are] unknown at this time." The resulting uncertainty has caused Plaintiffs—who are now unable to generate eggs of the same quality as when their eggs were extracted—to experience pain and suffering.

11. As to Prelude, Plaintiffs bring claims for negligence, premises liability, bailment, and violations of California's Unfair Competition Law ("UCL") arising out of Prelude's failure to adequately store and maintain Plaintiffs' eggs and embryos. Plaintiffs also assert omissions-based fraud claims against Prelude for failing to disclose that it had acquired control over storage of their eggs and embryos, that it lacks a medical or tissue bank license, and that the processes it had in place to protect Plaintiffs' tissue were inadequate. As to Chart, Plaintiffs assert claims for strict products liability, for negligent failure to recall, and under the UCL based on Chart's defective design and manufacture of Tank 4 and failure to warn of its defective nature. As to PFC, Plaintiffs assert omissions-based fraud claims arising out of PFC's failure to disclose that it had transitioned responsibility for egg and embryo storage to Prelude and that Prelude's prevailing systems and processes in place for safe storage were inadequate.

JURISDICTION AND VENUE

- 12. This Court has subject matter jurisdiction over this action under the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because (a) Plaintiffs are citizens of states different from Defendants; (b) the amount in controversy exceeds \$5,000,000, excluding interest and costs; (c) the proposed class consists of more than 100 individuals; and (d) none of the exceptions under the subsection applies to this action.
- 13. This Court has personal jurisdiction over Defendants. They conduct substantial business in California and intentionally availed themselves of the laws and markets of this state. A significant portion of the acts and omissions at issue occurred in California, and Plaintiffs and many class members suffered harm in California. Plaintiffs' claims against Defendants are meaningfully connected to California in that: (1) each Plaintiff had eggs or embryos stored at PFC, which is located in California and within the Prelude network; and (2) each Plaintiff had eggs or embryos stored in Chart's

24

25

26

27

28

tank, which was physically located at PFC's San Francisco facility, and which failed, resulting in damage to Plaintiffs.

14. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District.

INTRADISTRICT ASSIGNMENT

15. Assignment to the San Francisco Division is proper under Local Rules 3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in San Francisco.

PARTIES

A. Plaintiffs

- 16. Plaintiff A.B. is a citizen and resident of Wyandot County, Ohio.
- 17. Plaintiff C.D. is a citizen and resident of Wyandot County, Ohio.
- 18. Plaintiff E.F. is a citizen and resident of San Francisco County, California.
- 19. Plaintiff G.H. is a citizen and resident of San Francisco County, California.
- 20. Plaintiff I.J. is a citizen and resident of Contra Costa County, California.
- 21. Plaintiff K.L. is a citizen and resident of San Francisco County, California.
- 22. Plaintiff M.N. is a citizen and resident of San Francisco County, California.
- 23. Plaintiff O.P. is a citizen and resident of San Mateo County, California.
- 24. Given the sensitive nature of their claims and the services they purchased from PFC and Prelude, Plaintiffs are using initials in this litigation to protect their privacy. If so directed by the Court, Plaintiffs will seek permission to proceed under these pseudonyms.

B. Defendants

1. Prelude and Pacific MSO

- 25. At all relevant times, Defendant Prelude Fertility, Inc. was a Delaware corporation headquartered in Florida. Prelude operates the largest frozen donor egg bank in North America, in addition to a network of egg and embryo storage facilities—including PFC—across the country.
- 26. Prelude was founded in 2016 by startup entrepreneur Martin Varsavsky with a \$200 million investment by New York-based Lee Equity Partners. Prelude's stated business plan is to create

a national network of egg and embryo storage centers. According to Varsavsky, "What Prelude does is bridge the gap, it makes people's biology meet their psychology" through "The Prelude Method": "You freeze your gametes when fertile, thaw them and create embryos when ready, genetically sequence the embryos, and then transfer one embryo at a time. And you continue to do this until you achieve your desired number of children."

- 27. Prelude added PFC to its national network of fertility clinics and storage facilities in September 2017.
- 28. In conjunction with its transaction with PFC, on September 15, 2017, Prelude formed Pacific MSO, LLC, a wholly owned subsidiary, through which it conducted a portion of its PFC-based egg and embryo storage operation. Pacific MSO is a Delaware corporation with its principal executive office located at 55 Francisco Street, Suite 500—the same location as PFC's office.
- 29. Prelude describes "egg freezing, in vitro fertilization (IVF), genetic screening of embryos, and donor egg matching" as part of "Prelude's comprehensive services."
- 30. Prelude, independently or through its qualified subsidiary Defendant Pacific MSO, exercised control over the PFC egg and embryo storage operation at the time of the Tank 4 incident. At the time of the incident, the employees responsible for performing regular monitoring and maintenance of Tank 4 were employees of Prelude or Pacific MSO, LLC.
- 31. Neither Prelude nor Pacific MSO is licensed to provide medical services. Prelude and Pacific MSO provide only non-clinical (*i.e.*, non-medical) services and do not employ any physicians.

2. PFC

- 32. PFC is a private unincorporated entity located at 55 Francisco Street, Suite 500, San Francisco, California 94133.
- 33. PFC was founded in 1999 and advertises a full range of fertility services, including egg cryopreservation, IVF, genetic testing, "cutting-edge laboratory techniques and technology such as . . . vitrification," and storage of cryopreserved eggs and embryos.
- 34. At all relevant times, Plaintiffs' eggs and embryos were stored at a laboratory located at PFC's San Francisco facility.

35. At the time of the incident on March 4, 2018, Tank 4 was located at PFC's San Francisco facility.

3. Chart

- 36. Defendant Chart, Inc. is a Delaware corporation headquartered in Georgia.
- 37. Founded in 1992, Chart is a publicly traded global manufacturer of equipment used in the production, storage, and application of industrial gases. Chart produces a variety of cryogenic equipment. On its website, Chart states that its "focus is cryogenics." Chart claims that its products "utilize our proprietary vacuum and insulation technologies, including storage equipment," and that "[o]ur industry-proven core-competency provides the highest insulation thermal performance in cryogenics[.]" Chart holds itself out as "a recognized global brand for the design and manufacture of highly engineered cryogenic equipment" and a "leading global manufacturer of vacuum insulated products and cryogenic systems."
- 38. Chart, through its MVE brand, sells a line of cryogenic equipment that includes freezers and metal storage tanks. Chart claims that its MVE brand "is the benchmark for biological storage systems, used for the cryogenic preservation of human . . . tissues."
- 39. Chart states that its "cryobiological storage products include vacuum insulated containment vessels for the storage of biological materials." Chart describes the competition for cryobiological storage products as "significant" and notes that "competition in this field is focused on design, reliability, and price."
- 40. Chart designed and manufactured Tank 4, the storage tank in which Plaintiffs' eggs and embryos were stored on the date of the incident at issue in this lawsuit.

FACTUAL ALLEGATIONS

I. <u>Prelude Was Responsible for the Safe Storage of Plaintiffs' Eggs and Embryos at the Time of the Incident.</u>

41. Prelude claims that it is "on a mission" to provide "the best options, science, and care so everyone can have the opportunity to be a mom or dad when they are ready." According to Martin Varsavsky, Prelude's Founder and Executive Chairman, and self-described "serial tech entrepreneur":

The Prelude method is for anyone who would like to have healthy babies when they are ready. To increase the chances of having healthy babies when they are ready. Right now we live in a society in which we leave to chance one of the most important aspects of our life which is to have children. We leave it to chance and frequently we face adverse outcomes. What we want is . . . for people to have healthy babies in a reliable way. . . . To work on your career when you want to work on your career, to do your maternity when you want to do your maternity

- 42. As alleged below, as of September 2017 Prelude had responsibility for the safe storage of Plaintiffs' eggs and embryos. Safe storage requires maintaining functional alarm, monitoring, liquid nitrogen autofilling, and backup systems—all safety measures PFC represented on its website that it had in place to ensure the safe storage of Plaintiffs' eggs and embryos.
 - A. Background on Cryopreservation and Freezer Storage.
- 43. Cryopreservation is the process of vitrifying (freezing) eggs and embryos and is conducted by personnel after a doctor has retrieved the necessary biologic material from a patient. Freezer storage is the service that provides for the storage of the vitrified eggs or embryos and is overseen by non-clinical personnel. Freezer storage facilities are often in different locations from the clinics where doctors retrieve the biologic material, and sometimes are even in different locations from the facilities where the cryopreservation was performed.
- 44. Successful storage of eggs and embryos requires stocking the storage facility with the necessary and appropriate equipment (such as tanks, controllers, liquid nitrogen autofillers, and alarms), properly maintaining that equipment, logging the results of regular inspections, and adhering strictly to the systems and protocols in place to protect against harm to eggs and embryos that may result from tank failure, changes in temperature, or declining liquid nitrogen levels.
- 45. Stocking a storage facility with the proper equipment and strictly following the designated protocols is of critical importance given the value of human eggs and embryos to the individuals and families who deposit them for safekeeping.
- 46. Human eggs, also known as oocytes, are a limited resource. According to PFC, a woman has about one million eggs at birth, and this supply diminishes at the rate of about 1,000 per month, beginning at her birth. This decline is part of the natural aging process and is commonly referred to as a woman's biological clock. The loss of oocytes from the ovaries continues in the absence of menstrual cycles, and even when women are pregnant, nursing, or taking oral contraceptives. In addition, as PFC

26

acknowledges on its website, egg quality diminishes with time, with miscarriages and chromosomal abnormalities occurring more frequently for women who are older at the time of pregnancy. By their early-to-mid 40s, it becomes very difficult for women to conceive a child naturally.

- 47. The purpose of egg and embryo cryopreservation and storage is to allow women and their reproductive partners to preserve their reproductive material so that they may be fertilized (for eggs) and implanted (for embryos) at a later time. Prelude highlights egg freezing on its website as a means of preserving options, and allowing women to "[f]ind that right person. Focus on your career. Finish your education. . . . Freeze your eggs to preserve your option to build a family when you're ready. . . Set it and forget it until you're ready."
- 48. PFC emphasizes on its website and in sales and marketing materials that egg and embryo cryopreservation and storage allows for flexibility in family planning. That, in turn, PFC notes, gives women freedom, including the freedom to wait for the right child-rearing partner or to focus on their careers during their most fertile years.
 - В. PFC markets cryopreservation and freezer storage services as an insurance policy.
- 49 According to its website, PFC provides egg and embryo cryopreservation services (up until the point of storage) as a means of preserving "a precious resource, limited to just a few years of your life[,]" and further states that cryopreserving eggs and embryos "can increase your chances of conception by 5 to 10 times."
- 50. PFC—through its website—emphasizes that people like Plaintiffs can achieve flexibility and insurance in family planning by purchasing its services:
 - 6 Reasons to Preserve Your Fertility Today! (1) For a future family . . . (2) To allow for educational pursuits . . . (3) To have time to develop a business or career . . . (4) To give your relationship time to mature . . . (5) To reduce the risk of medical treatments that might impact fertility . . . (6) To achieve control over your future.
- 51. PFC also promotes—on its website and in sales and marketing materials—its egg and embryo cryopreservation services to people diagnosed with infertility, which it describes as a "workable challenge."

- 52. Infertility is defined as the inability to conceive after one year of unprotected intercourse if a woman is under the age of 35, or after six months if a woman is 35 or older.
- 53. For many individuals and couples experiencing infertility, PFC's embryo cryopreservation services represented their only hope of having a biological child or of having children who are biological siblings.
 - C. PFC represented on its website, and in sales and marketing materials, that it would keep Plaintiffs' eggs and embryos safe in a state-of-the-art facility.
- 54. Before Plaintiffs' purchases of cryopreservation and storage services, PFC—on its website and in its sales and marketing materials—emphasized (and it continues to emphasize today) that eggs and embryos will be safely stored, indefinitely, for future family planning. The below representations can all be found on PFC's website and existed there prior to Plaintiffs' purchases of frozen storage services.
- 55. PFC states that its customers' "[e]ggs remain frozen until you need them" and that "there is no limit to how long cells remain viable in the frozen state."
- 56. Regarding embryos, PFC similarly explains that some customers "have come back after 10-15 years and the embryos have been thawed successfully and created healthy babies."
- 57. PFC claims that its facility is state of the art, meeting a "gold standard," and that it has a large and experienced staff dedicated to the "care and well-being of eggs, embryos and sperm."
- 58. The main techniques to cryopreserve eggs and embryos have been slow freezing and vitrification. With slow freezing—first used in 1986—it takes about two hours for eggs to reach final storing temperature. Starting in the mid-2000s, eggs and embryos began to be preserved through a rapid cryopreservation process called vitrification.
- 59. Vitrification is a more advanced and reliable technology that PFC describes as being "used in the embryo and egg freezing process so that they can be stored for later use." PFC states the newer vitrification process is safer than earlier slow-freezing technologies, which could lead to crystallization threatening the viability of cryopreserved tissue. "Avoiding ice formation in this way," PFC represents, "successfully protects the embryos from damage and allows them to be warmed later

giving survival rates consistently above 90%." "Over 90% of frozen eggs, on average, survive the freeze-thaw process" according to PFC.

- 60. PFC further states that all eggs and embryos are stored in vacuum-lined liquid nitrogen tanks—"like a large thermos flask"—that "are computer controlled and monitored 7 days a week with a dedicated alarm system."
- 61. PFC claims that liquid nitrogen "is very stable and easy to work with" and that each tank is equipped with numerous sensors to monitor temperature increases above –196°C or a drop in the level of liquid nitrogen. PFC also represents that the sensors "are connected to a telephone alarm system that will alert staff to an alarm condition outside of normal working hours. . . . The alarm system is tested weekly and continues to run on battery power in the event of a power failure. The alarm system can also be checked remotely." When a tank alarm goes off, the on-call embryologist is supposed to arrive within 30 minutes regardless of time of day and must conduct a physical inspection of the tank before the alarm can be turned off.
- 62. PFC further claims that, in addition to constant electronic monitoring, each tank "gets a physical inspection daily, looking for problems or signs of problems," and that the amount of nitrogen in the tank "is assessed as a means of monitoring for a possible slow leak or an impending tank failure."
- 63. On its website, PFC emphasizes its use of liquid nitrogen autofillers, which it represents are needed because the nitrogen in the tanks continuously evaporates at a slow rate:

Embryos and sperm in freezers don't actually need power at all, provided that we physically fill the cryo tanks with liquid nitrogen once or twice a week. The computers that usually monitor and automatically fill these tanks do need power of course, but they are not essential to maintain refrigeration.

- 64. PFC also emphasized on its website that a functional monitoring, alarm, and autofilling system mitigated any risk presented to Plaintiffs' eggs and embryos, explaining that computerized controllers were constantly monitoring and addressing any issues: "the computer is monitoring and maintaining the liquid nitrogen levels most of the time in the same way that the autopilot on an airplane does most of the flying."
 - 65. PFC likewise advertises the durability of its tanks and storage facility on its website:

The storage tanks require no power and would not be impacted by a power failure or blackout. They are made of metal and would probably survive a small or moderate fire. If the tanks were not physically damaged or knocked over in a disaster, they should survive intact. Even if no one was able to physically check the tanks, or if we were unable to obtain liquid nitrogen, the tanks should still maintain their temperature for several days.

- D. PFC Relinquished its Storage Operation to Prelude in September 2017 Without Advising Plaintiffs.
- 66. Plaintiffs and class members engaged PFC to provide egg retrieval, embryo creation, and cryopreservation services. Many also paid PFC for long-term storage of their eggs and embryos after the cryopreservation services were complete.
- 67. In September 2017, without advising Plaintiffs, PFC entered into a series of agreements with Prelude through which PFC relinquished responsibility over tissue storage to Prelude, an unlicensed, venture-backed start-up network of fertility centers, and its wholly non-clinical (*i.e.*, non-medical) employees.
 - 68. Under PFC's agreements with Prelude:
- a. Prelude is identified as "responsible for determining the method, details and means of performing [egg and embryo storage] Services";
- b. The Prelude personnel responsible for the egg and embryo storage services "will not be employees of PFC "; and
- c. PFC and Prelude "are not, and will not be deemed to be, joint venturers, partners, employees or agents of each other. Neither party will have any authority to bind the other without the other party's express written consent Neither party will control or direct the methods by which the other party and the respective personnel will perform their duties and obligations under this Agreement, except to the extent required by applicable law or the PFC Policies."

| 69. | |
|-----|--|
| | |
| | |
| | |
| | |

- 70. Prelude is a non-medical entity, has no license to perform medical services, and has no doctors on staff. Concurrently with the Prelude-PFC transaction—months before the Tank 4 incident—Prelude's subsidiary, Pacific MSO, amended its articles of incorporation to reflect that "[t]he Corporation is no longer engaging in the profession of medicine"
- 71. PFC did not disclose to Plaintiffs the existence of Prelude or the fact that PFC had transferred control over egg and embryo storage to Prelude. Prelude also did not disclose that it had acquired control over tissue storage, that it was unlicensed, or that its employees were wholly non-medical.

II. <u>Precision and Care Are Required in the Retrieval, Cryopreservation and Storage of Eggs and Embryos.</u>

- A. The process of retrieving and storing eggs and embryos is demanding, time consuming, and expensive.
- 72. People who engage in fertility services and cryopreservation make large monetary and emotional investments. They endure painful and invasive procedures, financial stress, and the strain the process puts on their mental health and relationships with others, all in the hopes that one day they will be able to have a child.
- 73. Women take drug and hormone cocktails and injections over several weeks to stabilize the uterine lining, stimulate ovaries into producing follicles, and stop these ovary follicles from releasing eggs. Then, after an ovulation trigger injection, eggs are collected under sedation or a general anesthetic. A woman may be subjected to multiple injections each day, resulting in bruising, swelling, and discomfort. The drug and hormone therapy may also trigger other side effects, such as tiredness, nausea, headaches, and blood clots, as well as negative emotions. The process can limit travel and other activities, and often requires time off from work. The retrieval procedure itself requires insertion of a thick needle through the vaginal wall to drain the ovary follicles of their fluid. After the procedure, a woman often experiences residual pain for about a week and may need bed rest for several days. Some women suffer significant side effects, such as ovarian hyperstimulation syndrome, requiring hospitalization.

- 74. PFC acknowledges on its website that undergoing egg retrieval is "emotionally trying" and physically demanding. PFC recognizes that "the time and energy that is needed, both physically and emotionally can drain even the staunchest crusader."
- 75. Infertility is associated with anger, depression, anxiety, marital problems, and loss of self-esteem among prospective parents. PFC warns customers online that they may experience intense anger, despair, and guilt, and that it is "is very common to experience symptoms of anxiety and depression as a result of this experience."
- 76. The egg retrieval process compounds these emotions and stresses. For many, this process represents their last hope for having children. Each cycle can produce anxiety and fear that not enough eggs will be retrieved, or that the eggs retrieved will not be of a high enough quality. Multiple cycles are often required. Many women experience and express strong feelings of anxiety, failure, hopelessness, and disappointment during this process.
- 77. Prelude is also aware of the vulnerability experienced by individuals going through the egg retrieval and embryo creation process.
- 78. Egg retrieval, embryo creation, and cryopreservation services are costly. Customers pay more than \$8,000 for a single cycle of egg retrieval, which includes clinical monitoring, cryopreservation, and one year of storage. Additional cycles cost \$6,995 each. On its website, PFC recommends storing more eggs than a woman typically produces in a single cycle. It is not uncommon for women to undergo three or more egg retrieval cycles.
- 79. Embryo creation services are even costlier: PFC charges \$11,595 for basic IVF, including clinical monitoring, egg retrieval, lab processing, and embryo transfer. If a customer chooses to use Comprehensive Chromosome Screening to select the healthiest embryo to transfer, PFC's basic IVF cost rises to \$16,085.
- 80. After freezing, Plaintiffs and other customers paid approximately \$600 per year for Prelude's storage of their eggs or embryos.
- 81. The above amounts do not include the costs of in-person consultations (\$375 each consultation), pre-cycle lab work, egg cryopreservation medications (\$2,000–\$6,000), embryo transferring (\$2,845–\$4,460), and embryo transfer medications (\$300–\$600). Customers typically also

pay thousands of dollars for fertility drugs leading up to egg retrieval, and often spend hundreds of dollars on acupuncture and other services recommended to improve outcomes. The entire process often costs tens of thousands of dollars.

- B. The loss of eggs and embryos results in emotional distress, pain, and suffering.
- 82. Prelude and PFC are aware of the lengths to which people go to obtain eggs and embryos, how much these eggs and embryos mean to their customers, the customers' emotional (and financial) investment in the survival of the eggs and embryos, and the customers' expectations that great care will be taken to preserve and protect the eggs and embryos to avoid irreparable harm.
- 83. As women age, the quantity and quality of their eggs diminish. The most determinative factor in IVF success is the woman's age when her eggs were extracted. At some point, usually around her mid-40s, a woman can no longer produce viable eggs. Even if additional eggs can be retrieved, one cannot replace 35-year-old eggs with 40-year-old eggs and expect the same result. When eggs and embryos are damaged or compromised, it may be impossible for customers to have their own biological children. There is no possibility of creating substitute embryos for cancer survivors or those whose spouses have died. Likewise, those who used donor eggs or sperm to create embryos may find it impossible to retrieve additional material from the same donors. Thus, donor-users who already have children may be prevented from having additional children who are biologically related to their siblings.
- 84. The success or failure of egg and embryo cryopreservation and storage services has substantial emotional and psychological ramifications for those seeking to become parents. Losing eggs or embryos results in severe emotional distress for the owner.
 - C. Successful cryopreservation and storage depend on strict adherence to protocols.
- 85. Eggs and embryos are fragile. They must be handled and stored carefully. Cooling, storing, warming, and removing cryoprotectants must follow precise, controlled protocols. Failure to adhere to these protocols can render the egg or embryo nonviable, impair implantation and viability, and introduce chromosomal abnormalities.
- 86. A key goal of cryopreservation is to reduce cellular damage caused by the formation of ice crystals and the expansion of water as cryopreserved material cools to subzero temperatures. PFC

states on its website that "[t]he key to successful egg freezing is determining a technique that will not damage the fragile chromosomes of the egg"; this is because "the chromosomes of the egg are vulnerable to damage, including damage from the exertion of the freezing and thawing process."

- 87. As noted above, two primary cryopreservation technologies have emerged. Both rely upon cryoprotectants, which are solutions added to the cells that reduce cell damage by displacing water in a manner similar to antifreeze. The first technology, slow freezing (also known as slow programmable freezing), utilizes specialized equipment that lowers the temperature of embryos conditioned with cryoprotectants in a slow, controlled manner to -190° C. The second and newer technology, vitrification, refers to any process resulting in "glass formation"—that is, transformation from a liquid to a hardened liquid with minimal crystallization (ice crystals). According to PFC's website, vitrification "cools the cells in the embryo at rates close to 5,000 degrees per minute[,]" and "embryos that are vitrified are exposed to 5-10 times more cryoprotectant than slow frozen embryos." The ultra-rapid nature of this process minimizes (1) the formation of ice crystals and (2) toxicity damage to the cells that cryoprotectants can cause during longer exposure to warmer temperatures.
- 88. The process of warming eggs and embryos that have been preserved through cryopreservation is similarly precise and dependent on specialized techniques and chemical solutions. PFC describes the embryo warming process as follows on its website: "embryos coming out of the freezer (at -196°C) are warmed to room temperature in a maximum of three seconds. This rapid warming method minimizes damage to the embryo from ice crystals that can form during warming." A key part of the warming procedure is the precise dilution and eventual replacement of the toxic cryoprotectant fluid with a solvent compatible with cytoplasmic fluid. PFC also states on its website that it "incubat[es] the embryo in decreasing concentrations of the antifreeze, and increasing concentrations of water. Over a period of 15 minutes, the embryo is stepped through 3 different solutions, until finally the antifreeze is gone and all the water has been replaced."
- 89. For slow-frozen tissue, the failure to thaw slowly can result in cells over-expanding, rupturing, and dying. For vitrification, it is important to warm quickly to avoid ice formation. Thus, it is critical that eggs or embryos cryopreserved through slow freezing be thawed slowly, and that tissue cryopreserved through vitrification be warmed quickly in a carefully controlled manner. An

uncontrolled rise in temperature in a storage tank, like the one at issue here, can have catastrophic consequences for eggs and embryos.

III. Prelude Caused Irreparable Harm to Plaintiffs by Failing to Protect Their Eggs and Embryos.

- 90. On March 4, 2018, Prelude discovered a loss of a substantial amount of liquid nitrogen in one of the cryogenic storage tanks located at PFC, Tank 4, manufactured by Chart. This incident affected thousands of cryopreserved eggs and embryos belonging to more than 400 individuals and families.
 - A. Prelude should have had systems and processes in place to ensure that Plaintiffs' eggs and embryos were not damaged.
- 91. Liquid nitrogen in cryopreservation tanks evaporates at a slow rate. Absent extreme circumstances, even when a leak occurs it should take days for a tank to warm enough to cause damage to the enclosed eggs and embryos.
- 92. Egg and embryo storage facilities have developed and implemented a variety of systems and processes to protect against liquid nitrogen levels dropping to levels low enough to endanger customers' eggs and embryos. These systems and processes include maintaining a functional controller that constantly monitors temperature and liquid nitrogen levels, conducting regular inspections of the tank and controller to verify controller functionality and accuracy, deploying multiple alarm systems (both local and remote) that detect and send alerts of low liquid nitrogen levels, and installing autofillers that detect and automatically replenish low liquid nitrogen levels.
- 93. On its website and in sales and marketing materials, PFC told its customers that the storage facility located at its San Francisco headquarters was state of the art, containing tanks equipped with around-the-clock monitoring, alarm systems, and response protocols, with further protection from daily walk-throughs. But no alarms or phone alerts notified Prelude of the March 4 malfunction. Instead, an unidentified Prelude employee discovered the problem while working in the lab. Staff then transferred the eggs and embryos from Tank 4 to another tank.
- 94. Prelude lacked monitoring, alarm, and response systems and processes sufficient to detect and prevent harm from a dangerous temperature rise in Tank 4. Prelude has not explained why

Tank 4 was not equipped with a controller that detected problems with the tank's temperature and liquid nitrogen level and consumption, why staff did not detect problems with Tank 4 during walk-throughs prior to March 4, or why Prelude did not have a functional autofilling mechanism on Tank 4 to replenish low liquid nitrogen levels.

- 95. Prelude (and in the first instance, PFC) further failed to mitigate the risk of loss of stored reproductive material by failing to store multiple eggs and embryos belonging to a single customer in separate vials and tanks.
- 96. *Wired* interviewed one laboratory director who opined that Prelude should have done just that:

"It's really quite sad the samples weren't split up," says Nahid Turan, who directs laboratory operations at the Coriell Institute for Medical Research, one of the oldest and largest biobanks in the US. "They were literally putting all the eggs in one basket." In addition to having samples in multiple tanks at their New Jersey facility, Coriell also has back-up sites in multiple locations around the country. And its software engineers built real-time monitoring systems to flag any tanks trending in a troubling direction *before* they fail.

- 97. Cryopreserved eggs and embryos belonging to many hundreds of other people were stored in the same tank as Plaintiffs' tissue. Tank 4 housed up to 15% of the total cryopreserved tissue located at PFC's San Francisco facility, consisting of thousands of eggs and embryos.
- 98. Most people with eggs and embryos stored in Tank 4 had all of their eggs and embryos stored in that single tank.
 - B. Chart recalled cryostorage tanks for vacuum seal defects after the Tank 4 incident.
- 99. On April 23, 2018, Chart, the manufacturer of Tank 4, recalled certain cryostorage tanks, stating in its recall notice: "Chart is presently investigating the possible cause of the VACUUM LEAK AND/OR FAILURE which may be due to inadequate adhesion of the composite neck to the aluminum unit" (emphasis in original). Chart added that the "issue appears to be an isolated occurrence involving the machine and binding agent used during the manufacturing process."
- 100. Chart announced the recall four days after PFC's April 19 email to its customers revealed the conclusion of "independent experts" that the March 4 incident "likely involved a failure of the tank's vacuum seal."

C. Multiple investigations were opened after the Tank 4 incident.

101. Various government entities and trade groups have responded to the March 4, 2018 incident. The College of American Pathologists (CAP) is conducting a formal investigation into the incident, as is the California Department of Public Health. The American Society for Reproductive Medicine also is studying the incident and has stated that it intends to make recommendations to its members based on its findings.

D. Prelude's failure to keep Plaintiffs' eggs and embryos safe and secure has resulted in harm.

- 102. As a result of Prelude's deficient performance of their storage duties, Plaintiffs have suffered serious, lifelong harm and lost the family planning flexibility that caused them to cryopreserve their eggs and embryos in the first place.
- 103. Prelude has refused to share publicly the data it has collected regarding the number of Tank 4 eggs and embryos that have been thawed or the resulting outcomes. The survival rate for these eggs and embryos is *far* lower than it would have been had the incident not occurred.
- 104. PFC has taken the position that the embryos in Tank 4 must be fully thawed to determine whether they remain viable after the incident. PFC also asserts that the eggs in Tank 4 must be fully thawed and fertilized to determine whether they remain viable after the incident. Because of the risks associated with re-freezing embryos, a family must be prepared before thawing to transfer the embryo into a woman's uterus and attempt a pregnancy if the embryo is deemed viable.
- 105. Many of those affected by the Tank 4 incident have attempted to thaw their eggs or embryos, only to confirm that their eggs or embryos are no longer viable. Many families and individuals have lost their best or only chance of having a child. Those who can undergo additional retrievals face a greater risk that those eggs or embryos will not lead to a successful pregnancy, as the age at which a woman's eggs are retrieved is the dominant factor for rates of success or failure.
- 106. Neither PFC nor Prelude has provided a comprehensive analysis of the risks of attempting a pregnancy with any of the tissue from Tank 4, including the risks that the drop in liquid nitrogen levels may have caused chromosomal or other defects undetectable from a thaw. In fact, after

the Tank 4 incident, PFC has told its customers that pregnancies derived from material stored in Tank 4 may face "unknown" risks.

- 107. Nevertheless, PFC has advised Plaintiffs with affected eggs and embryos to attempt pregnancies with Tank 4 tissue. Before undergoing an embryo or egg thaw, embryo transfer, or egg fertilization, PFC requires customers to sign a consent statement acknowledging that the risks are uncertain and waiving any liability on the part of PFC arising out of the thaw, transfer, or fertilization procedure.
- Thus, as a result of the Tank 4 incident, Plaintiffs are being asked to make consequential reproductive decisions immediately—depriving them of the freedom and flexibility they sought when they decided to store their frozen eggs and embryos. To determine whether their tissue remains viable, PFC has counseled those affected by the incident to thaw and immediately fertilize eggs, and to transfer embryos to a woman's uterus. Yet the purpose of cryopreservation was to allow these customers to make reproductive choices on their own timelines. Many customers do not yet have a partner with whom they wish to fertilize their eggs, or are not ready to move forward with a sperm donor, much less try to get pregnant now or arrange for a surrogate. Others were busy with their careers and other commitments when the incident occurred, making it inconvenient or impossible to attempt a pregnancy right away.
- 109. People affected by the March 4 incident have described being thrust into a state of limbo, as the "insurance policy" they paid for has vanished. To restore their future fertility options, some are attempting additional retrieval cycles at an older age, with lower-quality eggs, and at considerable cost, burden, and disruption to their lives. These additional retrieval cycles also involve medical risks and potential complications. Many class members completed these cycles only to learn they were incapable of producing sufficient, or any, viable eggs or embryos. Other class members, for whom additional retrievals are not possible or recommended, fear that they will remain childless.
- 110. The National Infertility Association recognized the negative impact of the March 4 incident on women and families, stating that it was "shocked" to hear of this "unprecedented traged[y]" for "the entire family building community. Our hearts break for each person impacted. We know first-

hand what someone goes through to have eggs or embryos to freeze, and to have this outcome is devastating for everyone."

- 111. The Tank 4 incident has exacted an enormous emotional toll on Plaintiffs, who are distraught.
- 112. Given the sensitive nature of the eggs and embryos entrusted to their care, as well as their familiarity with the deeply emotional aspects of their services, PFC and Prelude were aware of the substantial adverse consequences for PFC's customers that would result from a failure to keep their eggs and embryos safe and secure.
 - E. PFC's communications regarding the incident have compounded the harm.
- 113. PFC first attempted to notify its customers of the March 4 incident a week after it occurred.
- 114. At approximately 4:00 a.m. Pacific time on March 11, 2018, PFC sent its customers an email stating:

Earlier this week, a single piece of equipment lost liquid nitrogen for a brief period of time. The remainder of the equipment and cryo-storage facility was not affected. As soon as the issue was discovered, our most senior embryologists took immediate action to secure all tissue in that single cryo-storage tank. The tank was immediately retired, and the facility is operating securely.

We have hired independent experts and launched an in-depth investigation of the matter. We felt it was imperative to advise you that your tissue was stored in the affected tank and *may* have been impacted. Based on our preliminary analysis, the good news is that we do expect that some of the tissue from that tank remains viable. We are continuing to gather information but wanted to share these developments with you directly.

- 115. The email further stated, "[w]e are incredibly sorry that this happened and for the anxiety that this will surely cause. We are heartbroken by this situation and our thoughts are with each of you who may have been touched by this event."
- 116. The email invited Plaintiffs and other families with eggs and embryos stored in Tank 4 to call to discuss the incident with their fertility specialists. The call center was overwhelmed for

weeks, and the information provided over the phone and in person has been vague and often inconsistent. Different PFC staff members have provided customers with conflicting information.

- 117. PFC did not provide further written information until over a month later, on April 19, 2018, when it wrote to its customers with "several updates following the tank failure that occurred in the embryology lab on March 4, 2018."
- 118. PFC wrote that "independent experts have been investigating the incident" and preliminarily determined that it "likely involved a failure of the tank's vacuum seal."
- 119. PFC did not—in either its initial March 11 communication or its April 19 follow up—disclose to Plaintiffs, or to anyone else with tissue stored at its facility, that Prelude had and continues to have control over egg and embryo storage.
- 120. PFC's public messages have exacerbated Plaintiffs' pain and confusion. On March 11, 2018, a PFC employee told ABC News that a large number of families with eggs and embryos stored at the facility were "people who won't use them anyway." Other customers with eggs and embryos in Tank 4 were billed for storage fees after the incident occurred and before it was disclosed to them.
- 121. While PFC has offered some of its customers a free additional cycle for egg retrieval, such a remedy is not adequate to compensate for the incident. Older women are generally not able to produce eggs of as high a quality as when they were younger, and in many cases go through the entire process only to learn they are unable to produce any viable eggs. Even where some eggs can be retrieved, women confront a greater risk that those eggs will not lead to a successful transfer and pregnancy. Moreover, additional retrievals are time consuming, expensive, physically painful, and emotionally exhausting, and typically require time away from work. Even two or three cycles may not fully replenish the number of viable eggs that were lost.
- 122. PFC's April 19, 2018 email blaming the incident on a failure of Tank 4's vacuum seal left Plaintiffs with more questions than answers. PFC did not say why it failed to detect the incident until it was too late to prevent harm to Plaintiffs' eggs and embryos. Plaintiffs were not told why no alarm alerted storage staff, why a backup system (*e.g.*, an autofill function or additional generator) did not engage, or why the problem went undiscovered until March 4.

123. PFC states on its website that tanks can go without power or liquid nitrogen for "several days" without compromising the enclosed reproductive tissue. It is unclear why Prelude failed to detect the problem with Tank 4 until it was too late.

- 124. PFC's April 19 email also stated that it "can report several early pregnancies" from thawed and transferred embryos, and that it had "successfully thawed a limited number of eggs[,] confirm[ing] that there is viable tissue from the tank." PFC did not disclose to its customers, however, that much of the tissue in the tank is *unviable*. Nor did PFC provide a comparison of the survival rate of affected tissue to the survival rate of eggs and embryos under normal circumstances. PFC still has not publicly provided this information. Instead, PFC notified all people with tissue in Tank 4, including Plaintiffs, that their eggs and embryos might be "viable" despite knowing this was *not* true for many or most of these people.
- 125. PFC's failure to communicate clearly and consistently with victims of the Tank 4 incident has compounded the harm caused by the incident.

PLAINTIFF-SPECIFIC ALLEGATIONS

Plaintiffs A.B. and C.D.

- 126. Plaintiffs A.B. and C.D. first contacted PFC in or around May 2013 about the possibility of creating embryos and having their embryos frozen.
- 127. In July 2013 Plaintiffs A.B. and C.D. hired PFC to create and preserve their embryos for future use.
- 128. Before freezing their embryos at PFC, Plaintiffs A.B. and C.D. conducted extensive research concerning IVF and fertility centers and chose PFC based on the belief that it provided high-quality services that were state of the art. Before having their embryos cryopreserved with PFC, Plaintiffs A.B. and C.D. saw representations about PFC's services on its website, including PFC's claims that it provided high-quality services. Plaintiffs A.B. and C.D. also had both phone and inperson consultation sessions with Dr. Eldon Shriock in May and June 2013. During these sessions, Dr. Shriock told Plaintiffs A.B. and C.D. about PFC's care, professionalism, and state-of-the-art facilities.
- 129. Over the course of the summer of 2013, Plaintiffs A.B. and C.D. underwent procedures to prepare for embryo creation and cryopreservation.

- 130. Before the egg retrieval procedure in August 2013, Plaintiff A.B. went through a month of treatment and injections. PFC ultimately retrieved approximately twenty-two of her eggs, which were then fertilized with Plaintiff C.D.'s sperm.
- 131. At the time of the March 4, 2018 incident, Plaintiffs A.B. and C.D. had four healthy, viable cryopreserved embryos.
- 132. At the time of the Tank 4 incident, Plaintiffs A.B. and C.D.'s embryos were under Prelude's protection, custody, and control.
- 133. Prelude kept Plaintiffs A.B. and C.D.'s embryos within a metal storage tank—Tank 4—at PFC's San Francisco facility. Rather than mitigating the risk of tank failure by spreading Plaintiffs A.B. and C.D.'s embryos among several tanks, Prelude stored all of Plaintiffs A.B. and C.D.'s embryos in the same tank.
- 134. Plaintiffs A.B. and C.D. paid approximately \$32,242.30 for the creation of their embryos in 2013, of which \$25,200 was paid directly to PFC. They have since paid \$600 annually for their embryos' storage.
- 135. Plaintiffs A.B. and C.D. experienced severe emotional distress when they learned of the March 4, 2018 incident and in the months that have followed.

Plaintiff E.F.

- 136. Plaintiff E.F. first contacted PFC in or around May 2016 about the possibility of having her eggs frozen.
- 137. In or around June 2016, Plaintiff E.F. hired PFC to retrieve and preserve her eggs for future use.
- 138. Before having her eggs frozen with PFC, Plaintiff E.F. saw representations about PFC's services on its website, including claims regarding the qualifications of PFC's staff and the science behind the clinic's procedures. Plaintiff E.F. also met with Dr. Carolyn Givens, who told her about PFC's use of cutting-edge technology and assured her that her eggs would be there for as long as she needed them.

13

17 18

19 20

21 22

23 24

27

26

25

28

- 139. In the summer of 2016, Plaintiff E.F. underwent procedures to prepare for egg cryopreservation. Before the retrieval procedure, she went through two months of treatment and injections. PFC ultimately retrieved and cryopreserved approximately nine of her eggs.
- 140. At the time of the Tank 4 incident, Plaintiff E.F.'s eggs were under Prelude's protection, custody, and control.
- Prelude kept Plaintiff E.F.'s eggs within a metal storage tank—Tank 4—at PFC's San 141. Francisco facility. Rather than mitigating the risk of tank failure by spreading Plaintiff E.F.'s eggs among several tanks, Prelude stored all of her eggs in the same tank.
- Plaintiff E.F. has paid approximately \$11,000 for the retrieval and storage of her eggs. 142. She experienced severe emotional distress when she learned of the March 4, 2018 incident and in the months that have followed.

Plaintiff G.H.

- Plaintiff G.H. first contacted PFC in or around February 2016 about the possibility of 143 having her eggs frozen.
- In or around April 2016, Plaintiff G.H. hired PFC to retrieve and preserve her eggs for 144. future use.
- 145. Before having her eggs frozen with PFC, Plaintiff G.H. saw representations about PFC's services on its website, including claims about the quality of its services. Plaintiff G.H. also met with Dr. Carolyn Givens, who provided information regarding PFC's services.
- In the spring of 2016, Plaintiff G.H. underwent procedures to prepare for egg retrieval and cryopreservation. Before the retrieval procedure, she went through two months of treatment and injections. PFC ultimately retrieved and cryopreserved approximately two of her eggs.
- At the time of the Tank 4 incident, Plaintiff G.H.'s eggs were under Prelude's 147. protection, custody, and control.
- 148. Prelude kept Plaintiff G.H.'s eggs within a metal storage tank—Tank 4—at PFC's San Francisco facility. Rather than mitigating the risk of tank failure by spreading Plaintiff G.H.'s eggs among several tanks, Prelude stored all of her eggs in the same tank.

149. Plaintiff G.H. has paid approximately \$14,500 for the retrieval and storage of her eggs. She experienced severe emotional distress when she learned of the March 4, 2018 incident and in the months that have followed.

Plaintiff I.J.

- 150. Plaintiff I.J. first contacted PFC in or around November 2012 about the possibility of having her eggs frozen.
- 151. In or around December 2012, Plaintiff I.J hired PFC to retrieve and preserve her eggs for future use.
- 152. Before freezing her eggs with PFC, Plaintiff I.J. saw representations about PFC's services in PFC's brochure, including claims that PFC "had a very strong embryo freezing program" and that its customers "can avoid high order multiple pregnancies by transferring fewer fresh embryos and successfully freezing the remaining embryos." Plaintiff I.J. also saw representations that PFC "devoted considerable time and effort into assembling one of the most highly trained teams in the country." Plaintiff I.J. met with staff at PFC who assured her that her eggs would be there for as long as she needed them.
- 153. In February 2013, Plaintiff I.J. underwent procedures to prepare for egg retrieval and cryopreservation. Before the retrieval procedure, she went through two months of treatment and injections. PFC ultimately retrieved and cryopreserved approximately 17 of her eggs.
- 154. At the time of the Tank 4 incident, Plaintiff I.J.'s eggs were under Prelude's protection, custody, and control.
- 155. Prelude kept Plaintiff I.J.'s eggs within a metal storage tank—Tank 4—at PFC's San Francisco facility. Rather than mitigating the risk of tank failure by spreading Plaintiff I.J.'s eggs among several tanks, Prelude stored all of her eggs in the same tank.
- 156. Plaintiff I.J. has paid approximately \$17,000 to PFC and Prelude for procedures, medications, and storage of her eggs. She experienced severe emotional distress when she learned of the March 4, 2018 incident and in the months that have followed.

Plaintiff K.L.

- 157. Plaintiff K.L. first contacted PFC on or around June 3, 2010, about the possibility of having her eggs cryopreserved.
- 158. In or around December 2015, Plaintiff K.L. hired PFC to retrieve and preserve her eggs for future use.
- 159. Before having her eggs frozen with PFC, Plaintiff K.L. saw representations about PFC's services on its website, including PFC's claims that the clinic and its services were safe and reliable, and that eggs could be stored until the right time for the customer. Plaintiff K.L. also saw PFC's representations that the process was quick and easy for customers and had a very high likelihood of success. In addition, Plaintiff K.L. met with Dr. Eldon Schriock, who told her that storage at PFC was safe.
- 160. In February 2016, Plaintiff K.L. underwent procedures to prepare for egg retrieval and freezing. Before the retrieval procedure, she went through months of treatment and injections. She also had to take several days off from work and could not travel for work for two weeks. PFC ultimately retrieved and froze five of her eggs.
- 161. At the time of the Tank 4 incident, Plaintiff K.L.'s eggs were under Prelude's protection, custody, and control.
- 162. Prelude kept Plaintiff K.L.'s eggs from her first cycle within a metal storage tank—Tank 4—at PFC's San Francisco facility. Rather than mitigating the risk of tank failure by spreading Plaintiff K.L.'s eggs from that cycle among several tanks, Prelude stored all of her eggs in the same tank.
- 163. Plaintiff K.L. has paid approximately \$12,000 to PFC and Prelude for procedures, medications, and storage of her eggs. She experienced severe emotional distress when she learned of the March 4, 2018 incident and in the months that have followed.

Plaintiffs M.N. and O.P.

- 164. Plaintiff M.N. first contacted PFC in or around September 2011 about the possibility of having her eggs frozen.
- 165. In or around late 2011, Plaintiff M.N hired PFC to retrieve and preserve her eggs for future use.

- 166. Before having her eggs frozen with PFC, Plaintiff M.N. saw representations about PFC's services on its website, including claims regarding its success rates and ability to help people have a family and plan for the future. Plaintiff M.N. also met with Dr. Eldon Schriock, who told her about PFC's statistics and success rates.
- 167. In January 2012, Plaintiff M.N. underwent procedures to prepare for egg freezing. She went through months of invasive and time-consuming treatments, including injections, blood tests, and ultrasounds. She underwent approximately three retrieval cycles, yielding approximately 37 eggs.
- 168. In 2016, Plaintiff M.N. hired PFC to fertilize half of her eggs with a sperm donor, resulting in three embryos. Her remaining 15 eggs were stored in Tank 4.
- 169. At the time of the Tank 4 incident, Plaintiff M.N.'s remaining eggs were under Prelude's protection, custody, and control.
- 170. Prelude kept M.N.'s eggs within a metal storage tank—Tank 4—at PFC's San Francisco facility. Rather than mitigating the risk of tank failure by spreading Plaintiff M.N.'s eggs among several tanks, Prelude stored all of her eggs in the same tank.
- 171. In December 2017, after Plaintiff M.N. met her reproductive partner, O.P., M.N. and O.P. hired PFC to fertilize M.N.'s remaining eggs with O.P.'s sperm to create embryos. In consultation with PFC specialists, M.N. and O.P. decided to proceed with the fertilization by mid-2018.
- 172. Plaintiff M.N. has paid more than \$25,000 to PFC and Prelude for procedures, medications, and storage of her eggs. Plaintiffs M.N. and O.P. experienced severe emotional distress when they learned of the March 4, 2018 incident and in the months that have followed.

* * *

173. PFC had multiple opportunities—on its website, in written correspondence, over the phone and in person—to inform Plaintiffs that it had transferred control over egg and embryo storage to Prelude and that Prelude's protocols and equipment were inadequate to protect against damage to their eggs and embryos. Prelude had similar opportunities, including through its personnel's communications with class members, to accurately describe who was responsible for storage and the nature of the safeguards that were in place. Nevertheless, despite knowing (1) that PFC had transferred control over tissue storage to Prelude, and (2) that Prelude's standards, systems, and processes were inadequate to

protect Plaintiffs' eggs and embryos, PFC and Prelude did not accurately disclose the nature and details of their tissue storage operation to Plaintiffs.

174. Had either or both PFC and Prelude disclosed that Prelude had taken control of PFC's egg and embryo storage operation or that the Prelude's storage monitoring and alarm systems and other processes were deficient, nonfunctional, or incapable of protecting their eggs and embryos in the event of a tank failure, Plaintiffs would not have purchased or continued using the egg and embryo storage services.

CLASS ACTION ALLEGATIONS

175. Plaintiffs propose certification of the following class, pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure:

All individuals, and their reproductive partners, who had eggs, embryos, or other material in Tank 4 at Pacific Fertility Center in San Francisco, California on March 4, 2018.

Excluded from this class are Defendants, their affiliates and subsidiaries, and their officers, directors, partners, employees, and agents; class counsel, employees of class counsel's firms, and class counsel's immediate family members; defense counsel, their employees, and their immediate family members; and any judicial officer who considers or renders a decision or ruling in this case, their staff, and their immediate family members.

- 176. <u>Numerosity</u>. The members of the class are so numerous that their individual joinder is impracticable. There are more than 400 class members, whose names and addresses are readily available from PFC's records.
- 177. Existence and Predominance of Common Questions of Fact and Law. Class certification is appropriate under Rule 23(b)(3) because this action involves common questions of law and fact that predominate over any questions affecting individual class members, including, without limitation:
- a. Whether Tank 4 was defective, including due to Chart's manufacturing or design of the tank;
- b. Whether Prelude owed a duty to Plaintiffs and class members to protect the eggs and embryos under its care;

- c. Whether the March 4, 2018 loss of liquid nitrogen in Tank 4 resulted from Prelude's negligence or other wrongful conduct;
- d. Whether Prelude failed to take adequate and reasonable measures to ensure that its systems were protected;
- e. Whether Prelude failed to take available steps to ensure that liquid nitrogen levels in its storage tanks would remain sufficient;
- f. Whether Prelude breached its duties to protect the eggs and embryos that Plaintiffs and class members entrusted to its care;
- g. Whether PFC and Prelude fraudulently concealed material information regarding egg and embryo storage, practices, and procedures;
- h. The type(s) and measure(s) of compensable and other redressable injury incurred by Plaintiffs and class members as a result of Defendants' conduct alleged herein; and
- i. What measures are necessary to ensure that eggs and embryos stored at PFC are properly safeguarded in the future.
- 178. <u>Typicality</u>. Plaintiffs' claims are typical of the other class members' claims because Plaintiffs and class members were subjected to the same wrongful conduct and damaged in the same way by having their eggs and embryos compromised.
- 179. Adequacy of Representation. Plaintiffs are adequate class representatives. Their interests do not conflict with the interests of the other class members they seek to represent. Plaintiffs have retained counsel competent and experienced in complex class action litigation, as well as in matters concerning egg and embryo loss, who will prosecute this action vigorously. Plaintiffs and their counsel will fairly and adequately pursue and protect the interests of the class.
- 180. <u>Superiority</u>. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The sensitive, private nature of the facts involved here, as well as the fear that bringing an individual suit could affect future treatment at PFC, favors providing a class vehicle to adjudicate these claims. The damages or other financial detriment suffered by Plaintiffs and the other class members are relatively small compared to the burden and expense that would be

required to individually litigate these claims. As a result, it would be impracticable for class members to seek redress individually. Individualized litigation would also create a potential for inconsistent or contradictory judgments and increase the delay and expense to all parties and the court system. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

- 181. Class certification is also appropriate under Rule 23(b)(2) because Defendants acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief with respect to the members of the class as a whole.
- 182. The claims of class members include common issues whose efficient adjudication in a class proceeding would materially advance the litigation and aid in achieving judicial economy and efficiency. Hence, in the alternative, class certification under Rule 23(c)(4) may be appropriate as to certain issues.

CLAIMS FOR RELIEF

- 183. Plaintiffs bring each of the following claims under California law.
- 184. None of Plaintiffs' claims involves any allegation of medical malpractice.

FIRST CAUSE OF ACTION

Negligence and/or Gross Negligence (Against Prelude and Pacific MSO)¹

- 185. Plaintiffs incorporate the above and below allegations by reference.
- 186. This is not a claim for professional negligence. Neither Prelude nor Pacific MSO is a health care provider. At no relevant time has Prelude been licensed or certified to provide medical services. In September 2017, concurrently with the PFC transaction, Pacific MSO amended its articles of incorporation to make clear that it was not engaged in the practice of medicine; thus, like Prelude, Pacific MSO has at no relevant time been licensed or certified to provide medical services.
- 187. Given the special relationship arising from the sensitive services they undertook to perform—storage of human egg and embryos—Prelude and Pacific MSO owed Plaintiffs a duty to

¹ For the sake of clarity, Prelude and Pacific MSO are referred to separately hereinafter.

exercise reasonable care in all aspects of the storage of Plaintiffs' eggs and embryos so as to avoid destroying them, damaging them, or jeopardizing their viability given that doing so would inevitably lead to emotional distress. Egg and embryo storage services are intertwined with Plaintiffs' most vital concerns, such as comfort, happiness, and personal welfare.

- 188. Prelude and Pacific MSO also owed a duty to Plaintiffs because they undertook provision of egg and embryo storage services from PFC for a charge. Such services were of a kind that Prelude and Pacific MSO should have recognized and did recognize as needing to be performed with reasonable care for the protection of Plaintiffs' emotional tranquility and peace of mind.
- 189. Plaintiffs' harms occurred in the course of specified categories of activities, undertakings, or relationships in which negligent actions and negligent failures to act were especially likely to cause serious harm.
- 190. It was reasonably foreseeable to Prelude and Pacific MSO that Plaintiffs would experience severe emotional distress as a result of any breach of their duty of reasonable care.
- 191. Recognition that Prelude and Pacific MSO have a duty to avoid causing emotional distress and other harm will promote the policy of preventing future harm, by motivating Prelude and Pacific MSO to implement processes and systems reasonably likely to safeguard the eggs and embryos entrusted to them going forward. This duty also furthers the community's interest in ensuring that reliable long-term egg and embryo freezer storage services are available to those who wish to become parents one day in the future.
- 192. The burden on Prelude and Pacific MSO from a duty to avoid causing emotional distress is fair and appropriate, in light of the importance of the eggs and embryos they voluntarily agreed to store and protect, at considerable cost to Plaintiffs.
- 193. As detailed above, Prelude and Pacific MSO took actions that a reasonably careful person would not have taken in the same situation and also failed to take actions that a reasonably careful person would have taken in the same situation. Prelude and Pacific MSO therefore breached their duty to exercise reasonable care in the storage of Plaintiffs' eggs and embryos.

- 194. Prelude and Pacific MSO's acts and omissions constitute gross negligence, because they constitute a total lack of care and an extreme departure from what a reasonably careful person would do in the same situation to prevent foreseeable loss of eggs and embryos.
- 195. Prelude and Pacific MSO's carelessness and negligence directly and foreseeably damaged Plaintiffs. Prelude and Pacific MSO's mishandling of Plaintiffs' eggs and embryos naturally and foreseeably caused mental anguish and serious emotional distress, among other injuries, to Plaintiffs.
- 196. There is a very close connection between Prelude and Pacific MSO's conduct and Plaintiffs' injuries. Plaintiffs' emotional distress and other harms occurred because of Prelude and Pacific MSO's failure to act reasonably in all aspects of the storage of Plaintiffs' eggs and embryos.
- 197. Plaintiffs trusted that those responsible for storing their eggs and embryos would use reasonable care to safeguard them. Prelude and Pacific MSO's carelessness with this precious material, and ultimately, with Plaintiffs' careful plans for parenthood, amounts to despicable conduct.
- 198. Prelude and Pacific MSO acted, and failed to act, willfully and with conscious and reckless disregard for the rights and interests of Plaintiffs. Prelude and Pacific MSO's acts and omissions had a great probability of causing significant harm and in fact caused such harm.
- 199. Prelude and Pacific MSO's failure to use reasonable care in handling and safeguarding Plaintiffs' eggs and embryos was a substantial factor in causing Plaintiffs' harm.
- 200. Prelude and Pacific MSO's negligence was a substantial factor in causing Plaintiffs severe emotional distress, regardless of whether it is ever determined conclusively that the eggs and embryos in Tank 4 are no longer viable. Prelude and Pacific MSO's misconduct has irreparably breached trust and caused uncertainty, anxiety, and fear among Plaintiffs and other affected families over how to proceed without being informed as to the long-term effects from an egg or embryo's presence in Tank 4 during the incident.
- 201. As a direct and proximate result of Prelude and Pacific MSO's negligence, Plaintiffs suffered harm in an amount to be determined at trial, including serious emotional distress consisting of worry, shock, fright, horror, anguish, suffering, grief, anxiety, nervousness, embarrassment,

humiliation, and shame. A reasonable person would be unable to cope with the losses suffered by Plaintiffs.

SECOND CAUSE OF ACTION

Negligent Failure to Recall (Against Chart)

- 202. Plaintiffs incorporate the above and below allegations by reference.
- 203. Chart acted negligently by failing to recall, prior to the incident of March 4, 2018, the line of tanks that included Tank 4.
- 204. Chart designed, manufactured, assembled, produced, distributed, and/or sold this line of tanks.
- 205. Chart knew or reasonably should have known that, when used as intended, Tank 4 presented or was likely to present a danger to eggs and embryos. Chart knew or reasonably should have known that the vacuum seal on Tank 4 was vulnerable to breach, and that upon such breach liquid nitrogen levels would drop, causing the eggs and embryos stored inside the tank to reach dangerously elevated temperatures.
- 206. After Chart sold Tank 4 to PFC and before March 4, 2018, Chart knew or reasonably should have known that the tank's vacuum seal was susceptible to breaking. Nevertheless, at no point during this time period did Chart recall, repair, or warn of the danger posed by the tank.
- 207. A reasonable designer, manufacturer, distributor, or seller facing the same or similar circumstances as Chart, in the exercise of reasonable care, would have recalled Tank 4 to ensure eggs and embryos were not endangered.
- 208. Chart's failure to timely recall Tank 4 was a substantial factor in causing harm to Plaintiffs. Had Chart recalled Tank 4 before the incident, the other Defendants would not have used it, and it would not have failed while Plaintiffs' eggs were stored within it.

THIRD CAUSE OF ACTION Bailment

(Against Prelude and Pacific MSO)

209. Plaintiffs incorporate the above and below allegations by reference.

- 210. A bailment arises where possession, but not ownership, of property is transferred from one party, a bailor, to another, a bailee. Where the personal property of a bailor is delivered to a bailee, a duty of care is owed.
- 211. Prelude and Pacific MSO received for safekeeping Plaintiffs' irreplaceable personal property to be safely and securely kept for the benefit of Plaintiffs, and to be redelivered to them upon demand.
- 212. Plaintiffs agreed to pay, and did pay, substantial sums in exchange for the safekeeping of their eggs and embryos.
- 213. Prelude and Pacific MSO had a duty to exercise care in maintaining, preserving, and protecting Plaintiffs' eggs and embryos. Further, Prelude and Pacific MSO had a duty to return the eggs and embryos, undamaged, to Plaintiffs.
- 214. Because of Prelude and Pacific MSO's wrongful conduct, as set forth herein, the irreplaceable property of Plaintiffs was irreparably damaged, precluding its redelivery to them.
- 215. Prelude and Pacific MSO breached their duties to exercise care in the safekeeping of Plaintiffs' eggs and embryos and to return the eggs and embryos, undamaged, to Plaintiffs.
- 216. As a direct and proximate result of Prelude and Pacific MSO's breach of the foregoing duties, Plaintiffs have been deprived of the opportunity to use their eggs and embryos, and have suffered damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION Premises Liability (Against Prelude and Pacific MSO)

- 217. Plaintiffs incorporate the above and below allegations by reference.
- 218. At all relevant times, Prelude and Pacific MSO owned, leased, and/or occupied the property, premises, machinery, and equipment, including Tank 4, on the premises at 55 Francisco Street, Suite 500, San Francisco, California 94133.
- 219. At all relevant times, Prelude and Pacific MSO had a duty to exercise reasonable care to keep Plaintiffs' eggs and embryos in a reasonably safe condition and free from injury or harm.

- 220. At all relevant times, Prelude and Pacific MSO knew, or by reasonable inspection and monitoring should have known, of the defective condition of the premises, and specifically of Tank 4 and its accompanying equipment.
- 221. At all relevant times, Prelude and Pacific MSO were careless and negligent in the ownership, management, control, and maintenance of the aforementioned real property, such that Plaintiffs, whose cryopreserved eggs were under Prelude and Pacific MSO's care, were harmed.
- 222. By reason of the foregoing, and as a direct and legal cause thereof, Plaintiffs have suffered injury, loss, harm, and damages.

FIFTH CAUSE OF ACTION

Violations of the Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 et seq. (Against Prelude, Pacific MSO, Chart, and PFC)

- 223. Plaintiffs incorporate the above and below allegations by reference.
- 224. The UCL prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice."

Unlawful

225. This claim is asserted against PFC, Prelude, and Pacific MSO. PFC, Prelude, and Pacific MSO's conduct is unlawful in violation of the UCL, because—as set forth below in the Sixth Cause of Action—it violates the California Consumers Legal Remedies Act.

Unfair

- 226. This claim is asserted against Defendants Prelude, Pacific MSO, and Chart.
- 227. Prelude, Pacific MSO, and Chart's conduct is unfair because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.
- 228. Prelude and Pacific MSO voluntarily took responsibility for safeguarding Plaintiffs' eggs and embryos through long-term freezer storage in order to preserve Plaintiffs' options for procreation, parenting, or assisting others experiencing infertility. Prelude and Pacific MSO breached that trust and acted in an unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner by, among other things:

- a. failing to adequately maintain, inspect, monitor, and test the liquid nitrogen freezer tanks, including through a functional electronic tank monitoring system capable of detecting a rise in temperature or a drop in liquid nitrogen levels and promptly alerting staff to the immediate problem;
- b. permitting a leakage or tank failure to occur with respect to one of their liquid nitrogen storage tanks—Tank 4—containing human eggs and embryos;
 - c. failing to adequately inspect Tank 4 on a regular basis;
 - d. failing to establish, maintain, and properly activate alarms;
 - e. failing to establish, maintain, and properly activate backup redundancies;
- f. failing to establish, maintain, and properly activate the controller and/or autofill devices; and
- g. failing to properly safeguard the eggs and embryos in their care, including by implementing and abiding by appropriate protocols and procedures.
- 229. Chart acted unfairly, in an unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner, by, among other things:
- a. failing to adequately design Tank 4 to avoid catastrophic failure resulting in damage to or destruction of frozen reproductive materials, including eggs or embryos;
- b. failing to adequately manufacture Tank 4 to avoid catastrophic failure resulting in damage to or destruction of frozen reproductive materials, including eggs or embryos;
 - c. failing to adequately warn users concerning the risks presented by Tank 4; and
- d. failing to recall, prior to the Tank 4 incident, the line of tanks that included Tank 4.
- 230. As a direct and proximate result of Prelude, Pacific MSO, and Chart's unfair conduct violative of the UCL, Plaintiffs have suffered injuries in fact and lost money or property, and they seek appropriate relief under the UCL, including injunctive relief and restitution.
- 231. The gravity of the harm resulting from Prelude, Pacific MSO, and Chart's conduct far outweighs any conceivable utility of this conduct. There are reasonably available alternatives that would further Prelude, Pacific MSO, and Chart's legitimate business interests, such as implementing

adequate design, testing, manufacturing, warning, and recall protocols, and implementing reasonable protocols and procedures to prevent catastrophic failure.

232. Plaintiffs could not have reasonably avoided injury from Prelude, Pacific MSO, and Chart's unfair conduct. Plaintiffs did not know, and had no reasonable means of learning, that Prelude and Pacific MSO were responsible for egg and embryo storage, let alone that they were not properly safeguarding the eggs and embryos in their custody and control. Nor did Plaintiffs have occasion to know that Chart had supplied and failed to recall a defective storage tank.

Fraudulent

- 233. This claim is asserted against PFC, Prelude, and Pacific MSO. PFC, Prelude, and Pacific MSO's conduct is fraudulent in violation of the UCL because it was likely to mislead a reasonable consumer, in at least the following respects:
- a. When offering to provide long-term freezer storage services to Plaintiffs and class members, PFC knowingly and intentionally failed to disclose and actively concealed that it did not have reasonable processes and systems in place to safeguard Plaintiffs' and class members' eggs and embryos;
- b. PFC also knowingly and intentionally failed to disclose and actively concealed that it had ceded control over storage of Plaintiffs' and class members' eggs and embryos to Prelude and Pacific MSO—which had no medical or tissue storage license—and their non-clinical staff; and
- c. Prelude and Pacific MSO knowingly and intentionally failed to disclose and actively concealed: (1) that they had acquired control over the storage of Plaintiffs' eggs and embryos from PFC, had no license, and had no medical personnel on staff; and (2) that their systems and processes in place to safeguard the eggs and embryos were inadequate.
- 234. PFC had ample means and opportunities to alert Plaintiffs and class members at the outset to the fact that it was not employing reasonable processes and systems to safeguard Plaintiffs' eggs and embryos. Later, PFC also had the means and opportunity to alert Plaintiffs and class members to the fact that Prelude and Pacific MSO had obtained control over egg and embryo storage.
- 235. Prelude and Pacific MSO also had opportunities to disclose these facts to Plaintiffs, including through their employees, who consulted with customers concerning their tissue.

236. Despite these opportunities, PFC, Prelude, and Pacific MSO all independently failed to disclose the above information to Plaintiffs and the other members of the class. Had Defendants made those disclosures, Plaintiffs would not have purchased, or continued purchasing, the long-term freezer storage services at issue.

- 237. PFC had a duty to accurately disclose who was responsible for tissue storage, and to warn of the inadequacies in its tissue storage systems and processes, because it made partial representations concerning the egg and embryo storage operation in place at its facility. PFC volunteered specific information to Plaintiffs through advertising, on its website, and in documents that its storage services were high quality and reliable, including representations that a tank could go without power or liquid nitrogen for "several days" without damaging the tissue it contained. PFC also had exclusive and superior knowledge of the relevant facts, compared to Plaintiffs and class members, yet actively concealed the information rather than disclosing it.
- 238. Prelude and Pacific MSO were under a duty to disclose both the change in control over tissue storage, and that their storage systems and processes were inadequate, given their exclusive knowledge of these matters. Yet they actively concealed the information rather than disclosing it.
- 239. As a direct and proximate result of PFC, Prelude, and Pacific MSO's fraudulent conduct violative of the UCL, Plaintiffs have suffered injuries in fact and lost money or property, and they seek appropriate relief under the UCL, including injunctive relief and restitution.
- 240. Had PFC, Prelude, and Pacific MSO not made misleading statements and omissions regarding the control over, and the adequacy of, the relevant equipment, systems, and processes, Plaintiffs would not have purchased and continued purchasing the storage services. In the meantime, PFC, Prelude, and Pacific MSO generated more revenue than they otherwise would have, unjustly enriching themselves.
- 241. Plaintiffs were harmed, and PFC, Prelude, and Pacific MSO's misleading statements and omissions were a substantial factor in causing Plaintiffs' harm.
- 242. The requested injunction under the UCL will primarily benefit the interests of the general public. It will have the primary purpose and effect of prohibiting unlawful action and inaction

that threatens injury to members of the public who have placed, or who in the future place, reproductive tissue under Prelude or Pacific MSO's care or in one of Chart's tanks.

SIXTH CAUSE OF ACTION

Violations of the Consumers Legal Remedies Act, Cal. Civ. Code § 1750 et seq. (Against PFC, Prelude, and Pacific MSO)

- 243. Plaintiffs incorporate the above and below allegations by reference.
- 244. PFC, Prelude, and Pacific MSO is each a "person" as defined by Civil Code §§ 1761(c) and 1770 and have provided "services" as defined by Civil Code §§ 1761(b) and 1770.
- 245. Plaintiffs are "consumers" as defined by Civil Code §§ 1761(d) and 1770 and have engaged in "transaction[s]" as defined by Civil Code §§ 1761(e) and 1770.
- 246. PFC, Prelude, and Pacific MSO's acts and practices were intended to and did result in the continued sale of services to Plaintiffs, and those acts and practices violated Civil Code § 1770, including by:
 - a. passing off services as those of another;
 - b. misrepresenting the source of goods or services;
 - c. misrepresenting the affiliation, connection, or association with another;
- d. representing that their services had characteristics, uses, and benefits that they did not have:
- e. representing that their services were of a particular standard, quality, or grade, when they were not;
 - f. advertising services with intent not to sell them as advertised; and
- g. representing that the subject of a transaction had been supplied in accordance with a previous representation when it had not.
- 247. PFC, Prelude, and Pacific MSO's acts and practices violated the Consumers Legal Remedies Act because each of these Defendants failed to disclose information that was material to Plaintiffs' relevant transactions. For example:
- a. When offering to provide long-term freezer storage services to Plaintiffs and class members, PFC knowingly and intentionally failed to disclose and actively concealed that it did

not have reasonable processes and systems in place to safeguard Plaintiffs' and class members' eggs and embryos;

- b. PFC also knowingly and intentionally failed to disclose and actively concealed that it had ceded control over storage of Plaintiffs' and class members' eggs and embryos to Prelude and Pacific MSO—which had no medical or tissue storage license—and their non-clinical staff; and
- c. Prelude and Pacific MSO knowingly and intentionally failed to disclose and actively concealed: (1) that they had acquired control over the storage of Plaintiffs' eggs and embryos from PFC, had no license, and had no medical personnel on staff; and (2) that their systems and processes in place to safeguard the eggs and embryos were inadequate.
- 248. PFC had ample means and opportunities to alert Plaintiffs and class members at the outset to the fact that it was not employing reasonable processes and systems to safeguard Plaintiffs' eggs and embryos. Later, PFC also had the means and opportunity to alert Plaintiffs and class members to the fact that Prelude and Pacific MSO had obtained control over egg and embryo storage.
- 249. Prelude and Pacific MSO also had opportunities to disclose these facts to Plaintiffs, including through their employees, who consulted with customers concerning their tissue.
- 250. Despite these opportunities, PFC, Prelude, and Pacific MSO all independently failed to disclose the above information to Plaintiffs and the other members of the class. Had Defendants made those disclosures, Plaintiffs would not have purchased, or continued purchasing, the long-term freezer storage services at issue.
- 251. PFC had a duty to accurately disclose who was responsible for tissue storage, and to warn of the inadequacies in its tissue storage systems and processes, because it made partial representations concerning the egg and embryo storage operation in place at its facility. PFC volunteered specific information to Plaintiffs through advertising, on its website, and in documents that its storage services were high quality and reliable, including representations that a tank could go without power or liquid nitrogen for "several days" without damaging the tissue it contained. PFC also had exclusive and superior knowledge of the relevant facts, compared to Plaintiffs and class members, yet actively concealed the information rather than disclosing it.

- 252. Prelude and Pacific MSO were under a duty to disclose both the change in control over tissue storage, and that their storage systems and processes were inadequate, given their exclusive knowledge of these matters. Yet they actively concealed the information rather than disclosing it.
- 253. As a direct and proximate result of PFC, Prelude, and Pacific MSO's deceptive acts and practices in violation of the Consumers Legal Remedies Act, Plaintiffs have suffered actual damages. Had PFC, Prelude, and Pacific MSO not made misleading statements and omissions regarding the control over, and the adequacy of, the relevant equipment, systems, and processes, Plaintiffs would not have purchased and continued purchasing the storage services. In the meantime, PFC, Prelude, and Pacific MSO generated more revenue than they otherwise would have, unjustly enriching themselves.
- 254. Plaintiffs were harmed, and PFC, Prelude, and Pacific MSO's misleading statements and omissions were a substantial factor in causing Plaintiffs' harm.
- 255. Plaintiffs accordingly are entitled to equitable relief, reasonable attorneys' fees and costs, declaratory relief, and a permanent injunction enjoining PFC, Prelude, and Pacific MSO from their unlawful, fraudulent, and deceitful activity.
- 256. Moreover, the conduct of PFC, Prelude, and Pacific MSO set forth herein was reprehensible and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which PFC, Prelude, and Pacific MSO should be punished by punitive and exemplary damages in an amount according to proof. PFC, Prelude, and Pacific MSO's behavior evidences a conscious disregard for the safety of the eggs and embryos entrusted to them, and by extension, those who placed the eggs and embryos in their care, including Plaintiffs. PFC, Prelude, and Pacific MSO's conduct was and is despicable conduct and constitutes malice under Section 3294 of the California Civil Code. An officer, director, or managing agent of PFC, Prelude, and Pacific MSO personally committed, authorized, and/or ratified the reprehensible conduct set forth herein. Plaintiffs thus seek an award of punitive damages sufficient to penalize PFC, Prelude, and Pacific MSO.
- 257. Pursuant to Civil Code § 1782(a), on June 21, 2018, Plaintiffs—on their own behalf and on behalf of the class—sent letters to Prelude and PFC notifying them of their CLRA violations and affording them the opportunity to correct their business practices and rectify the harm they caused. Plaintiffs sent the CLRA notice via certified mail, return receipt requested, to PFC and Prelude's

principal places of business. These notices are attached to this Complaint as Exhibits 1 and 2. PFC, Prelude, and Pacific MSO failed to correct their business practices or provide the relief requested within 30 days. Therefore, Plaintiffs seek money damages under the CLRA.

258. In accordance with Civil Code § 1780(d), Plaintiffs' CLRA venue declarations are attached to this Complaint as Exhibits 3-9.

SEVENTH CAUSE OF ACTION

Fraudulent Concealment (Against PFC, Prelude, and Pacific MSO)

- 259. Plaintiffs incorporate the above and below allegations by reference.
- 260. PFC, Prelude, and Pacific MSO's acts and practices constitute fraudulent concealment because each of these Defendants failed to disclose information that was material to Plaintiffs' relevant transactions. For example:
- a. When offering to provide long-term freezer storage services to Plaintiffs and class members, PFC knowingly and intentionally failed to disclose and actively concealed that it did not have reasonable processes and systems in place to safeguard Plaintiffs' and class members' eggs and embryos;
- b. PFC also knowingly and intentionally failed to disclose and actively concealed that it had ceded control over storage of Plaintiffs' and class members' eggs and embryos to Prelude and Pacific MSO—which had no medical or tissue storage license—and their non-clinical staff; and
- c. Prelude and Pacific MSO knowingly and intentionally failed to disclose and actively concealed: (1) that they had acquired control over the storage of Plaintiffs' eggs and embryos from PFC, had no license, and had no medical personnel on staff; and (2) that their systems and processes in place to safeguard the eggs and embryos were inadequate.
- 261. PFC had ample means and opportunities to alert Plaintiffs and class members at the outset to the fact that it was not employing reasonable processes and systems to safeguard Plaintiffs' eggs and embryos. Later, PFC also had the means and opportunity to alert Plaintiffs and class members to the fact that Prelude and Pacific MSO had obtained control over egg and embryo storage.

- 262. Prelude and Pacific MSO also had opportunities to disclose these facts to Plaintiffs, including through their employees, who consulted with customers concerning their tissue.
- 263. Despite these opportunities, PFC, Prelude, and Pacific MSO all independently failed to disclose the above information to Plaintiffs and the other members of the class. Had Defendants made those disclosures, Plaintiffs would not have purchased, or continued purchasing, the long-term freezer storage services at issue.
- 264. PFC had a duty to accurately disclose who was responsible for tissue storage, and to warn of the inadequacies in its tissue storage systems and processes, because it made partial representations concerning the egg and embryo storage operation in place at its facility. PFC volunteered specific information to Plaintiffs through advertising, on its website, and in documents that its storage services were high quality and reliable, including representations that a tank could go without power or liquid nitrogen for "several days" without damaging the tissue it contained. PFC also had exclusive and superior knowledge of the relevant facts, compared to Plaintiffs and class members, yet actively concealed the information rather than disclosing it.
- 265. Prelude and Pacific MSO were under a duty to disclose both the change in control over tissue storage, and that their storage systems and processes were inadequate, given their exclusive knowledge of these matters. Yet they actively concealed the information rather than disclosing it.
- 266. As a direct and proximate result of PFC, Prelude, and Pacific MSO's misleading statements and omissions, Plaintiffs have suffered actual damages. Had PFC, Prelude, and Pacific MSO not made misleading statements and omissions regarding the control over, and the adequacy of, the relevant equipment, systems, and processes, Plaintiffs would not have purchased and continued purchasing the storage services. In the meantime, PFC, Prelude, and Pacific MSO generated more revenue than they otherwise would have, unjustly enriching themselves.
- 267. Plaintiffs were harmed, and PFC, Prelude, and Pacific MSO's misleading statements and omissions were a substantial factor in causing Plaintiffs' harm.
- 268. The foregoing acts and omissions of PFC, Prelude, and Pacific MSO were committed maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich PFC, Prelude, and Pacific MSO. PFC, Prelude, and Pacific

MSO's conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

EIGHTH CAUSE OF ACTION Strict Products Liability – Failure to Warn (Against Chart)

- 269. Plaintiffs incorporate the above and below allegations by reference.
- 270. Chart manufactured, distributed, and/or sold cryogenic equipment used at PFC, including Tank 4.
- 271. The cryogenic storage tank at issue had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific and medical community at the time of the manufacture, distribution, or sale of the cryogenic storage Tank 4.
- 272. The cryogenic storage Tank 4 was defective and unreasonably dangerous when it left Chart's possession because it did not contain adequate warnings, including warnings concerning the risk of defective seals that may result in catastrophic nitrogen loss, the risk of nitrogen loss and prevalence of this occurrence, the risk of a rise in temperature that can damage and/or cause destruction of eggs or embryos, the rate of failure of the cryogenic storage tanks in the preservation of eggs or embryos or other human tissue, and the need for maintenance, inspection, and/or replacement of the cryogenic storage tanks.
- 273. The potential risks presented a substantial danger when the cryogenic storage tank at issue was used or misused in an intended or reasonably foreseeable way. The ordinary consumer would not have recognized the potential for risks.
- 274. Chart had constructive notice or knowledge and knew, or in the exercise of reasonable care should have known, that the cryogenic storage Tank 4 was dangerous, had risks, and was defective in manufacture or design, including because it could cause nitrogen loss resulting in damage to or destruction of frozen reproductive materials, including eggs or embryos.
- 275. Chart failed to adequately warn or instruct concerning the potential risks of the cryogenic storage tank.

| 27 | 6. | It was foreseeable to Chart that failure to adequately warn about the risks of its |
|-------------|--------|--|
| cryogenic | stora | age tank would cause irreparable harm, including the type of emotional distress suffered |
| by Plaintif | ffs, w | whose eggs and embryos were stored therein. |

277. As a result of Chart's failures to adequately warn, Plaintiffs were harmed as described herein, regardless of whether it is ever determined conclusively that certain eggs and embryos in Tank 4 are not viable. The lack of sufficient instructions and warnings was a substantial factor in causing Plaintiffs' harm.

NINTH CAUSE OF ACTION Strict Products Liability – Manufacturing Defect (Against Chart)

- 278. Plaintiffs incorporate the above and below allegations by reference.
- 279. Chart manufactured, distributed, and/or sold the cryogenic storage Tank 4.
- 280. The cryogenic storage tank contained a manufacturing defect when it left Chart's possession.
- 281. Chart had constructive notice or knowledge and knew, or in the exercise of reasonable care should have known, that the cryogenic storage tank was dangerous, had risks, and was defective in manufacture, including because it could cause nitrogen loss resulting in damage to or destruction of frozen reproductive materials, including eggs or embryos.
- 282. As a result of the manufacturing defect in Tank 4, Plaintiffs were harmed as described herein, regardless of whether it is ever determined conclusively that certain eggs and embryos in Tank 4 are not viable.
- 283. The defective nature of the cryogenic storage tank was a substantial factor in causing Plaintiffs' harm.

TENTH CAUSE OF ACTION

Strict Products Liability – Design Defect – Consumer Expectations Test (Against Chart)

- 284. Plaintiffs incorporate the above and below allegations by reference.
- 285. Chart manufactured, distributed, and/or sold the cryogenic storage Tank 4.
- 286. The cryogenic storage tank did not perform as safely as an ordinary consumer would have expected it to perform when used or misused in an intended or reasonably foreseeable way.

- 287. Chart had constructive notice or knowledge and knew, or in the exercise of reasonable care should have known, that the cryogenic storage tank was dangerous, had risks, and was defective in design, including because it could cause nitrogen loss resulting in damage to or destruction of stored frozen reproductive materials, including eggs or embryos.
- 288. As a result of the design defect in Tank 4, Plaintiffs were harmed as described herein, regardless of whether it is ever determined conclusively that certain eggs and embryos in Tank 4 are not viable.
- 289. The cryogenic storage tank's failure to perform safely was a substantial factor in causing Plaintiffs' harm.

ELEVENTH CAUSE OF ACTION

Strict Products Liability – Design Defect – Risk-Utility Test (Against Chart)

- 290. Plaintiffs incorporate the above and below allegations by reference.
- 291. Chart manufactured, distributed, and/or sold the cryogenic storage Tank 4.
- 292. The benefits of this tank's design are not outweighed by its risks, considering the gravity of the potential harm resulting from the use of the tank, the likelihood that the harm would occur, the feasibility of an alternative safer design at the time of manufacture, and the disadvantages of an alternative design.
- 293. Chart had constructive notice or knowledge and knew, or in the exercise of reasonable care should have known, that the cryogenic storage tank was dangerous, had risks, and was defective in design, including because it could cause nitrogen loss resulting in damage to or destruction of frozen reproductive materials, including eggs or embryos.
 - 294. Plaintiffs were harmed because Tank 4 lost liquid nitrogen.
 - 295. Chart's design of the tank was a substantial factor in causing Plaintiffs' harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the class defined above, respectfully request that the Court:

| 1 | A. | Certify the class under Fed | eral Rules of Civil Procedure 23(a), (b)(2), (b)(3), | | | |
|----|--|----------------------------------|---|--|--|--|
| 2 | and/or (c)(4), as appropriate; appoint Plaintiffs as representatives of the class; and appoint the | | | | | |
| 3 | undersigned counsel | as class counsel; | | | | |
| 4 | B. | Award Plaintiffs compensa | tory, restitutionary, rescissory, general, consequential, | | | |
| 5 | punitive and exempl | ary damages in an amount to | be determined at trial; | | | |
| 6 | C. | Award prejudgment interes | st as permitted by law; | | | |
| 7 | D. | Enter an appropriate injunc | etion against Defendants and their officers, agents, | | | |
| 8 | successors, employe | es, representatives, and assign | ns; | | | |
| 9 | E. | Appoint a monitor and reta | in jurisdiction to ensure that Defendants comply with | | | |
| 10 | | | | | | |
| 11 | F. | Enter other appropriate equ | uitable relief; | | | |
| 12 | G. | Award reasonable attorney | s' fees and costs, as provided for by law; and | | | |
| 13 | Н. | Grant such other and further | er relief as the Court deems just and proper. | | | |
| 14 | | | R JURY TRIAL | | | |
| 15 | Plaintiffs der | nand a trial by jury on all issu | ues so triable. | | | |
| 16 | | <i>J J</i> | | | | |
| 17 | Dated: November 3 | 0, 2018 | Respectfully submitted, | | | |
| 18 | | , | By:/s/Adam E. Polk | | | |
| 19 | | | Dena C. Sharp (State Bar No. 245869) | | | |
| | | | Jordan Elias (State Bar No. 228731) Adam E. Polk (State Bar No. 273000) | | | |
| 20 | | | GIRARD SHARP LLP | | | |
| 21 | | | 601 California Street, 14th Floor | | | |
| 22 | | | San Francisco, CA 94108 | | | |
| | | | Tel: (415) 981-4800 | | | |
| 23 | | | Fax: (415) 981-4846 | | | |
| 24 | | | dsharp@girardsharp.com jelias@girardsharp.com | | | |
| | | | apolk@girardsharp.com | | | |
| 25 | | | | | | |
| 26 | | | Eric H. Gibbs (State Bar No. 178658) | | | |
| 27 | | | Dylan Hughes (State Bar No. 209113) Steven M. Tindall (State Bar No. 187862) | | | |
| | | | Amy M. Zeman (State Bar No. 273100) | | | |
| 28 | | | GIBBS LAW GROUP LLP | | | |
| | | | 47 | | | |

| 1 2 3 4 | 505 14th Street, Suite 1110 Oakland, CA 94162 Tel: (510) 350-9700 Fax: (510) 350-9701 ehg@classlawgroup.com dsh@classlawgroup.com smt@classlawgroup.com |
|------------------|---|
| 5 | amz@classlawgroup.com |
| 6 | Adam B. Wolf (State Bar No. 215914) |
| 7 | Tracey B. Cowan (State Bar No. 250053) PEIFFER WOLF CARR & KANE, A |
| 8 | PROFESSIONAL LAW CORPORATION |
| 9 | 4 Embarcadero Center, Suite 1400 |
| | San Francisco, CA 94111 Tel: (415) 766-3545 |
| 10 | Fax: (415) 402-0058 |
| 11 | awolf@pwcklegal.com |
| | tcowan@pwcklegal.com |
| 12 | |
| 13 | Elizabeth J. Cabraser (State Bar No. 083151) |
| | Lexi J. Hazam (State Bar No. 224457) |
| 14 | Sarah R. London (State Bar No. 267083) |
| 15 | Tiseme G. Zegeye (State Bar No. 319927) |
| | LIEFF CABRASER HEIMANN & BERNSTEIN, LLP |
| 16 | 275 Battery Street, 29th Floor |
| 17 | San Francisco, CA 94111 |
| 10 | Tel: (415) 956-1000 |
| 18 | Fax: (415) 956-1008 |
| 19 | ecabraser@lchb.com |
| 20 | lhazam@lchb.com |
| 20 | slondon@lchb.com |
| 21 | tzegeye@lchb.com |
| 22 | Interim Class Counsel |
| 23 | Joseph G. Sauder (pro hac vice) |
| | SAUDER SCHELKOPF LLC |
| 24 | 555 Lancaster Avenue |
| 25 | Berwyn, Pennsylvania 19312 |
| | Tel: (610) 200-0580 |
| 26 | jgs@sstriallawyers.com |
| 27 | Dlainsies, Comen |
| 28 | Plaintiffs' Counsel |
| 20 | 40 |
| | 48 |